

DUPLOSPRAY MIS Gas-assisted Endoscopic Applicator Quick Reference Guide



Instructions for Circulating Nurse – DUPLOSPRAY MIS Regulator

1

Position DUPLOSPRAY MIS System so the foot pedal is placed next to the surgeon's foot at time of application.

2

Attach black gas supply hose, located at back of regulator, to source of medical grade CO₂.

3

Set CO₂ pressure between 51-100 psi.

4

Attach spray set sterile filters to regulator. Connect the blue vent line filter to the blue female Luer and the clear gas line filter to the male Luer on the regulator. *For additional reference, attach filters according to graphics on regulator faceplate.*

5

While depressing foot pedal, adjust gas flow rate to 2 liters per minute. Check gas flow by noting height of ball in flow gauge while stepping on foot pedal.

**For Tech Support
Call 1-877-TISSEEL**

Instructions for Scrub Nurse – DUPLOSPRAY MIS Applicator

1

Thread sterile replaceable tip onto applicator using tip alignment tool.

2

For Topical Use Only

Firmly attach the applicator to the TISSEEL syringe hubs.

3

For Topical Use Only

Fasten the pull strap to the TISSEEL syringe holder to assure the spray applicator is tightly secured.

4

Attach gas supply line, clear Luer connector, to sterile applicator. Turn white locking collar counter clockwise to secure connection.

5

Attach patient vent line, red luer connector, to available female luer on trocar cannula vent valve. Ensure vent valve is fully open.

6

For Topical Use Only

Pass assembled TISSEEL [Fibrin Sealant] and spray applicator to surgeon for spray application. Pass the end of the connection tube with the sterile filters to circulating nurse.

Instructions for Surgeon – DUPLOSPRAY MIS System

1

Depress foot pedal to start gas flow prior to applying TISSEEL. Check gas flow gauge on regulator before inserting applicator into trocar. If flow level ball does not move when foot pedal is depressed, the applicator tip is occluded and should be replaced.

2

While activating foot switch, dispense TISSEEL through applicator tip by depressing DUPLOJECT plungers using slow, steady pressure. To stop spray delivery, release pressure on DUPLOJECT plungers while maintaining gas flow by holding down foot pedal for an additional 3-5 seconds to clear applicator tip.

- ### TIPS
- The patient vent line attached to the trocar cannula vent valve will only vent gas out when foot pedal is depressed. After connection to trocar cannula, ensure vent valve is fully open on trocar cannula prior to spray application.
 - If tip becomes occluded during use, remove plugged tip by unscrewing it counterclockwise. Using a sterile cloth, wipe any clotted material off exposed tube ends. Screw on new tip and tighten with tip alignment tool.
 - The twin-tube assembly can be easily separated as necessary to allow freedom of movement.

Selected Important Risk Information

- Air or gas embolism has occurred when using the spray device without fibrin sealant, or fibrin sealant was administered using pressurized gas. This may occur if a spray device is used at higher than recommended pressures and/or in close proximity to the tissue surface.

Please see Indications and Important Risk Information on the back.

Rx Only: For safe and proper use of the DUPLOSPRAY device, please refer to full device instructions for use included.





TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in patients undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.

Sealing: TISSEEL is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.

Important Risk Information for TISSEEL

For Topical Use Only. Do not inject TISSEEL directly into the circulatory system or into highly vascularized tissue. Intravascular application of TISSEEL can lead to intravascular coagulation, may result in life-threatening thromboembolic events, and may increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. Exercise caution to minimize the risk of intravascular application when using TISSEEL in surgery.

Do not use TISSEEL in individuals with a known hypersensitivity to aprotinin.

Do not use TISSEEL for the treatment of severe or brisk arterial or venous bleeding. In these situations, TISSEEL will be washed away in the flow of blood before hemostasis can be attained.

Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of TISSEEL. Such reactions may especially be seen if TISSEEL is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously.

Aprotinin is known to be associated with anaphylactic reactions. Even in the case of strict local application of aprotinin, there is a risk of anaphylactic reactions to aprotinin, particularly in the case of previous exposure.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions. Remove remaining product from the application site.

Air or gas embolism has occurred when fibrin sealant was administered using pressurized gas. This may occur if a spray device is used at higher than recommended pressures and in close proximity to the tissue surface.

When using the EASYSpray device, or an equivalent spray device for open surgical procedures cleared by FDA, TISSEEL must not be sprayed in enclosed body areas and must be sprayed onto only visible application sites.

TISSEEL is denatured when exposing to solutions containing alcohol, iodine or heavy metals. If any of these substances have been used to clean the wound area, the area must be thoroughly rinsed before the application of TISSEEL.

Apply TISSEEL as a thin layer by dripping or spraying using cannula or spray set. Excess clot thickness may negatively interfere with wound healing.

The safety and effectiveness of TISSEEL used alone or in combination with biocompatible carriers in neurosurgical procedures or other surgeries involving confined spaces have not been evaluated; its use in this setting is not FDA approved.

TISSEEL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see accompanying full Prescribing Information.

The information presented here has been taken directly from the
DUPLOSPRAY MIS Instructions For Use, PN 21281 Rev.A.

For Tech Support Call 1-877-TISSEEL (1-877-847-7335)

Baxter, Tisseel and Duploject are trademarks of Baxter International Inc.

RM0500B 04/2012

Baxter

Baxter International Inc.
One Baxter Parkway
Deerfield, Illinois 60015

www.baxter.com